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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,203	09/23/2003	Michael P. Wallace	03-247 (US01)	2638

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EXAMINER	
ROANE, AARON F	
ART UNIT	**PAPER NUMBER**
3739	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/669,203	WALLACE, MICHAEL P.	
	Examiner	Art Unit	
	Aaron Roane	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-14,16,18,19,25,26 and 37-42* is/are pending in the application.

4a) Of the above claim(s) *4,9,14,16 and 26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6-8,10-13,18,19,25 and 37-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/14/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the first material, bioactive agent and second material must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 6, 8, 10-13, 37 and 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ken et al. (USPN 5,853,418) in view Geremia et al. (USPN 5,108,407) and in further view of Wallace et al. (USPN 6,280,457).

Regarding claims 1, 6, 10, 11, 18, 19, 25, 37 and 39-42 Ken et al. disclose a vaso-occlusive device for treating a site within a patient's vasculature, the device comprising a helically wound coil (coiled formed by 102 and its analogous counterparts in the other embodiments) forming a lumen and formed of platinum (see col. 4, lines 47-60), a filament/heating member (first material) (108, 208 and 214 and their analogous counterparts in the other embodiments) disposed in the lumen, the heating member at least partially comprising a first highly resistive, ferrous material (contains iron), the first material that is embedded within the device and which may be heated by application of a source of energy external to a patient's body after the device is implanted at a treatment site in the patient's body, see col. 1-9, particularly col. 4, line 6 through col. 5, line 10 and figures 1A-11D. Ken et al. fail to disclose a bioactive agent that is activated or released

when the device is heated. Ken et al. disclose a number of detachment methods for releasing the coil, see col. 1, line 49 through col. 2, line 63 and figures 3A-4C and 10. Geremia et al. disclose a vaso-occlusive coil device and teach an alternate method of detaching the coil from the device by heating and braking a second material in the form of an adhesive bond between the coil itself and the rest of the device, see abstract, col. 4, lines 14 col. 5, line 15 and figures 1-9. Wallace et al. also disclose a vaso-occlusive coil device and teach that "the polymeric fiber covering the device are used as a carrier for bioactive molecules. Non-limiting examples of bioactive materials which increase cell attachment and/or thrombogenicity include both natural and synthetic compounds, e.g., collagen, fibrinogen, vitronectin, other plasma proteins, growth factors (e.g., vascular endothelial growth factor, "vEGF"), synthetic peptides of these and other proteins having attached RGD (arginine-glycine-aspartic acid) residues, generally at one or both termini. In addition, polynucleotide sequences encoding peptides (e.g., genes) involved in wound healing or promoting cellular attachment may also be used, see col. 12, lines 3-14. It should be noted the combination of Ken et al., Geremia et al. and Wallace et al. provides a coil that has a polymer/bioactive agent coating that is detached from the rest of the device by heating. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Ken et al., as taught by Geremia et al., to detach the coil from the device by heating and braking an adhesive bond between the coil itself and the rest of the device as an alternate detaching method, and as further taught by Wallace et al., to provide the coil with a polymeric coating having a bioactive agent in order to improve the vaso-occlusion treatment.

Regarding claims 2, 3, 12 and 13, Ken et al. in view Geremia et al. and in further view of Wallace et al. disclose the claimed invention, see Ken et al., col. 5, line 64 through col. 6, line 62 and figures 1A-2C.

Regarding claims 8 and 29, Ken et al. in view of Geremia et al. and in further view of Wallace et al. disclose the claimed invention. It can be clearly seen that (108 and all analogous counterparts in other embodiments) of Ken et al. is embedded in the element, see figures 1A-10.

Regarding claim 30, Ken et al. in view of Geremia et al. and in further view of Wallace et al. disclose the claimed invention.

Regarding claim 34, Ken et al. disclose the claimed invention, see col. 1-9, particularly col. 4, line 6 through col. 5, line 10 and figures 1A-11D.

Claims 18, 19 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ken et al. (USPN 5,853,418) in view Geremia et al. (USPN 5,108,407) and in further view of Wallace et al. (USPN 6,280,457) and still in further view of Lee et al. (USPN 6,059,815).

Regarding claims, 18, 19 and 25 Ken et al. disclose a vaso-occlusive device for treating a site within a patient's vasculature, the device comprising a helically wound coil (coiled

formed by 102 and its analogous counterparts in the other embodiments) forming a lumen and formed of platinum (see col. 4, lines 47-60), a filament/heating member (first material) (108, 208 and 214 and their analogous counterparts in the other embodiments) disposed in the lumen, the heating member at least partially comprising a first highly resistive, ferrous material (contains iron), the first material that is embedded within the device and which may be heated by application of a source of energy external to a patient's body after the device is implanted at a treatment site in the patient's body, see col. 1-9, particularly col. 4, line 6 through col. 5, line 10 and figures 1A-11D. Ken et al. fail to disclose a bioactive agent that is activated or released when the device is heated by application of a magnetic field. Ken et al. disclose a number of detachment methods for releasing the coil, see col. 1, line 49 through col. 2, line 63 and figures 3A-4C and 10. Geremia et al. disclose a vaso-occlusive coil device and teach an alternate method of detaching the coil from the device by heating and braking a second material in the form of an adhesive bond between the coil itself and the rest of the device, see abstract, col. 4, lines 14 col. 5, line 15 and figures 1-9. Wallace et al. also disclose a vaso-occlusive coil device and teach that "the polymeric fiber covering the device are used as a carrier for bioactive molecules. Non-limiting examples of bioactive materials which increase cell attachment and/or thrombogenicity include both natural and synthetic compounds, e.g., collagen, fibrinogen, vitronectin, other plasma proteins, growth factors (e.g., vascular endothelial growth factor, "vEGF"), synthetic peptides of these and other proteins having attached RGD (arginine-glycine-aspartic acid) residues, generally at one or both termini. In addition, polynucleotide sequences encoding peptides (e.g., genes) involved in wound

healing or promoting cellular attachment may also be used, see col. 12, lines 3-14. Finally, Lee et al. disclose an aneurysm occlusion device and teach the alternate/equivalence of laser, RF and magnetic inductive heating for heat release mechanisms, see col. 6, line 33 through col. 7, line 62. It should be noted the combination of Ken et al., Geremia et al. and Wallace et al. provides a coil that has a polymer/bioactive agent coating that is detached from the rest of the device by heating via a magnetic field. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Ken et al., as taught by Geremia et al., to detach the coil from the device by heating and braking an adhesive bond between the coil itself and the rest of the device as an alternate detaching method, and as further taught by Wallace et al., to provide the coil with a polymeric coating having a bioactive agent in order to improve the vaso-occlusion treatment, and as still further taught by Lee et al., to use laser, RF and magnetic field as alternate/equivalents for heat releasing the coil.

Claims 7 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ken et al. (USPN 5,853,418) in view Geremia et al. (USPN 5,108,407) and in further view of Wallace et al. (USPN 6,280,457) as applied to claims 1 and 37 above, and further in view of Lee et al. (USPN 6,059,815).

Regarding claims 7 and 38, Ken et al. in view Geremia et al. and in further view of Wallace et al. disclose the claimed invention except for explicitly reciting the external

energy source comprising magnetic resonance. Lee et al. disclose an aneurysm occlusion device and teach the alternate/equivalence of laser, RF and magnetic inductive heating for heat release mechanisms, see col. 6, line 33 through col. 7, line 62. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Ken et al. in view of Geremia et al. in further view of Wallace et al., and as still further taught by Lee et al., to use laser, RF and magnetic field as alternate/equivalents for heat releasing the coil.

Response to Arguments

Applicant's arguments with respect to claims 1-3, 6, 7, 8, 10-13, 18, 19, 25 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (571) 272-4771. The examiner can normally be reached on Monday-Thursday 7AM-6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Aaron Roane A. R.
January 3, 2007

Roy D. Gibson
ROY D. GIBSON
PRIMARY EXAMINER